FDA U.S. Food and Drug Administration — Department of Health and Human Services

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

510(k) Premarket Notification Database

Device Classification Name	Mouthguard
510(K) Number	K053580
Device Name	DOCTOR'S NIGHTGUARD
Applicant	DENTAL CONCEPTS LLC. 555 Thirteenth Street, Nw Washington, DC 20004
Contact	Howard M Holstein
Classification Product Code	MQC
Date Received	12/22/2005
Decision Date	03/03/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 4/05/2007

EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2003

Dental Concepts LLC
C/O Mr. Michael Lesser
Medical Device Consultant, Incorporated
49 Plain Street
North Attleboro, Massachusetts 02760

Re: K024261
Trade/Device Name: Bite Plate
Regulation Number: None
Regulation Name: Dental Protector
Regulatory Class: Unclassified
Product Code: MQC
Dated: March 5, 2003
Received: March 6, 2003

Dear Mr. Lesser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital ,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K053580

Device Name: Doctor's® NightGuard™

Indications for Use:

The Doctor's NightGuard is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Prescription Use _____ AND/OR Over-The-Counter Use__X_
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

[illegible] General Hosp[illegible]
[illegible] Dental Devices

K053580

Page ___ of ___

K053580

MAR 3 2006

510(k) SUMMARY

Dental Concepts The Doctor's® NightGuard™

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Hogan & Hartson, LLP
555 13th Street, N.W.
Washington, D.C. 20004

Contact: Howard M. Holstein

Phone: (202) 637-5600
Facsimile: (202) 637-5910

Date Prepared: December 22, 2005

Name of Device and Name/Address of Sponsor

Doctor's® NightGuard™

Dental Concepts, LLC
650 From Road
Paramus, NJ 07652

Contact Person: Michael Lesser, President
Phone: (201) 225-2151
Facsimile: (201) 576-9780

Common or Usual Name

Dental Protector

Classification Name

Unclassified

Predicate Devices

Dental Concepts BruxGuard
Hollywood Products Mouth Peace
GEM Scientific Products, Inc. Tension Reliever

Intended Use / Indications for Use

The Doctor's NightGuard is indicated for protection against bruxism or nighttime teeth grinding. It is intended to reduce damage to the teeth and to prevent the noise associated with bruxing or grinding.

Technological Characteristics

The Doctor's NightGuard is composed of a soft, formable clear upper material, made of ELVAX® resin, a copolymer of ethylene and vinyl acetate, and a hard occlusal base, which cushions the teeth. The base is composed of Elvaloy®, a copolymer of ethylene and methyl acrylate containing 9% methyl acrylate. When heated and then briefly cooled, the upper material can be molded to fit the user's upper teeth. The hard base prevents bite-through by users with moderate to severe nocturnal bruxing. The shock absorbing polymer material cushions the teeth on all sides.

Performance Data

No performance data is required in support of this 510(k) notice.

Substantial Equivalence

The Doctor's NightGuard is as safe and effective as Dental Concepts' BruxGuard. The two devices are physically the same. The labeling for the Doctor's NightGuard has been revised to make it suitable for OTC use. Because the two devices are the same, the Doctor's NightGuard possesses the same technological characteristics and principles of operation and a similar intended use as the BruxGuard predicate device. The Doctor's NightGuard also has similar intended uses and indications as the Hollywood Products Mouth Peace and the GEM Scientific Products, Inc. Tension Reliever, which were sold over the counter, like the NightGuard. Thus, the Doctor's NightGuard is substantially equivalent.